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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,837	04/21/2004	Richard L. Gregory	7037-486	5846

7590

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/828,837	Applicant(s) GREGORY ET AL.	
	Examiner Iqbal Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Election/Restrictions

1. The inventions are distinct, each from the other because of the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I Claims 1-7, 16 and 17, drawn to a method for controlling dental plaque in the oral cavity of a host by using polypeptide murein hydrolase, classified in class 424, subclass 94.6.

II Claims 8-11, 18-23, drawn to a method of treating with oral composition, classified in class 424, subclass 50.

III. Claims 12-15, drawn to a method of lysing bacteria, classified in class 435, subclass 259.

IV. Claims 24-28 and 34-42, drawn to a polypeptide having murein hydrolase activity, classified in class 435, subclass 195.

V. Claims 29-33, drawn to polynucleotide encoding a polypeptide of SEQ ID NO: 6, expression vector, host cells and a process of producing of polypeptide, classified in class 536, subclass 23.2.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-V, one of the inventions (A) - (B)

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(A). Protein of SEQ ID NO: 6 or a nucleic acid encoding SEQ ID NO: 6.

(B). Protein of SEQ ID NO: 8 or a nucleic acid encoding SEQ ID NO: 8.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and V are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, Group I, which is a method for controlling dental plaque in the oral cavity of a host whereas invention V is a polynucleotide encoding polypeptide murein hydrolase. Polynucleotide of Group V is neither made nor used by the method of Group I.

3. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group IV which is a polypeptide murein hydrolase whereas Group I is a method for controlling dental plaque in the oral cavity of a host by using polypeptide murein hydrolase. The method for controlling dental plaque in the oral cavity of a host can be done by using other unrelated polypeptide such as dextranase.

4. Inventions V and II are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

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they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, Group V, which is polynucleotides encoding polypeptide murein hydrolase, and Group II is a method of using an oral composition. Polynucleotide of Group V is neither made nor used by the method of using an oral composition.

5. Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group IV, which is a polypeptide murein hydrolase whereas Group II is a method for treating with oral composition containing polypeptide murein hydrolase. The method for treating with oral composition for controlling dental plaque in the oral cavity of a host can be done by using other unrelated polypeptide such as dextranase.

6. Inventions V and III are unrelated, independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions directed to divergent molecules having different functions and effect. In this case, Group V, which is polynucleotides encoding polypeptide murein hydrolase, and Group III is a method of lysing bacteria. Polynucleotide of Group V is neither made nor used by the method of lysing bacteria.

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7. Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group IV, which is a polypeptide murein hydrolase whereas Group III is a method of lysing bacteria with polypeptide murein hydrolase. Using other unrelated polypeptide such as lysozyme can do the method of lysing bacteria.

8. The methods of Groups I, II and III are unrelated and patentably distinct as they comprise unrelated steps, use different products and produce different effects.

9. The nucleic acid and proteins of Group (A) - (B) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and polynucleotide encoding them. Therefore, where structural identity is required, such as for hybridization or expression or antibody binding, the different sequences have different effects.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

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process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Ph.D., Patent Examiner
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